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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 09/824,787 | 04/04/2001 | Maurice Zauderer | 1821.0040001/EKS/TJS | 2970 |
| 26111 | 7590 | 05/06/2003 | | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | EXAMINER | |
| | | | HARRIS, ALANA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---|-------------------------|
| Office Action Summary | Applicant No. | Applicant(s) |
| | 09/824,787 | ZAUDERER ET AL. |
| | Examiner Alana M. Harris, Ph.D. | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 38-166 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 38-166 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
- 1.) Certified copies of the priority documents have been received.
- 2.) Certified copies of the priority documents have been received in Application No. _____.
- 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>20</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

1. Claims 38-46, 83, 84, 122, 123 and 160-166 are generic to a plurality of disclosed patentably distinct species comprising distinct amino acid fragments of SEQ ID NO: 2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. amino acids S-9 to V-17 of SEQ ID NO:2, amino acids V-10 to V-17 of SEQ ID NO:2, amino acids E-16 to V-23 of SEQ ID NO:2, amino acids E-16 to R-24 of SEQ ID NO:2, amino acids E-16 to I-25 of SEQ ID NO:2, amino acids S-21 to Y-29 of SEQ ID NO:2, amino acids S-21 to F-35 of SEQ ID NO:2, amino acids G-22 to C-30 of SEQ ID NO:2, amino acids I-25 to C-30 of SEQ ID NO:2, amino acids C-30 to T-38 of SEQ ID NO:2, amino acids E-31 to Y-39 of SEQ ID NO:2, amino acids E-36 to A-43 of SEQ ID NO:2, amino acids A-37 to A-45 of SEQ ID NO:2, amino acids A-37 to V-46 of SEQ ID NO:2, amino acids T-38 to V-46 of SEQ ID NO:2, amino acids Y-39 to V-46 of SEQ ID NO:2, amino acids

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amino acids S-44 to I-53 of SEQ ID NO:2, amino acids A-45 to I-53; of SEQ ID NO:2, amino acids G-52 to L-59 of SEQ ID NO:2, amino acids E-54 to T-62 of SEQ ID NO:2, amino acids S-57 to F-75 of SEQ ID NO:2, amino acids R-58 to I-67 of SEQ ID NO:2, amino acids G-61 to I-69 of SEQ ID NO:2, amino acids G-63 to F-83 of SEQ ID NO:2, amino acids F-65 to L-73 of SEQ ID NO:2, amino acids E-66 to L-73 of SEQ ID NO:2, amino acids E-66 to V-74 of SEQ ID NO:2, amino acids I-67 to F-75 of SEQ ID NO:2, amino acids K-77 to Y-85 of SEQ ID NO:2, amino acids Q-72 to E-86 of SEQ ID NO:2, amino acids G-81 to L-89 of SEQ ID NO:2, amino acids F-83 to E-103 of SEQ ID NO:2, amino acids D-88 to A-96 of SEQ ID NO:2, amino acids L-89 to A-96 of SEQ ID NO:2, amino acids A-92 to T-101 of SEQ ID NO:2, amino acids R-95 to L-102 of SEQ ID NO:2, amino acids A-96 to K-104 of SEQ ID NO:2, amino acids K-104 to C-112 of SEQ ID NO:2, amino acids K-104 to V-113 of SEQ ID NO:2, amino acids I-105 to V-113 of SEQ ID NO:2, amino acids I-105 to I-114 of SEQ ID NO:2.

Species a.-oo. represents a distinct amino acid fragment and prior art on one would not be prior art on another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 38-46, 83, 84, 122, 123 and 160-165 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

**ALANA HARRIS
PATENT EXAMINER**

Alana M. Harris, Ph.D.
April 29, 2003